IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

MEDICAID and MEDICARE ADVANTAGE PRODUCTS ASSOCIATION OF PUERTO RICO, INC., *et al.*, *Plaintiffs,* v. **DOMINGO EMANUELLI HERNÁNDEZ, in his official capacity as Secretary of Justice of Puerto Rico, *et al.*,** *Defendants.*	**CIVIL NO. 20-1760 (DRD)**

OPINION AND ORDER

Pending before the Court is a *Motion for Judgment on the Pleadings* (Docket No. 47) filed by Plaintiffs, Medicaid and Medicare Advantage Products Association of Puerto Rico, Inc. (hereinafter, "MMAPA"), MMM Healthcare, LLC (hereinafter, "MMM"), Triple-S Advantage, Inc., Triple-S Salud, Inc., Triple S-Vida, Inc. (hereinafter, collectively "Triple-S"), MCS Advantage, Inc. (hereinafter, "MCS"), First Medical Health Plan, Inc. (hereinafter, "First Medical"), Humana Insurance of Puerto Rico and Humana Health Plans of Puerto Rico, Inc., (hereinafter, collectively "Humana") (hereinafter collectively, "Plaintiffs"). Defendants Domingo Emanuelli-Hernández and Alexander Adams Vega, in their official capacities as the Commonwealth of Puerto Rico's Attorney General and Insurance Commissioner, respectively, filed a *Response in Opposition* thereto. See Docket No. 53. A *Reply* and *Surreply* ensued shortly thereafter. See Docket Nos. 60 and 64.

Upon review, and for the reasons stated herein, the Court hereby **GRANTS** Plaintiffs' *Motion for Judgment on the Pleadings* (Docket No. 47) and accordingly, a dismissal of this case is warranted.

INTRODUCTION

The instant action stems from the Commonwealth of Puerto Rico's approval of Act 138-2020 (2020 P.R. Laws 138) and Act 142-2020 (2020 P.R. Laws 142), which set new standards for the operation of health plans throughout the Commonwealth, including those operated under the Medicare Advantage program, Medicare Part D, the Federal Employee Retirement Income Security Act of 1974 (hereinafter, "ERISA"), and the Federal Employees Health Benefits program (hereinafter, "FEHB"). Specifically, Act 138-2020 imposes obligations on insurers related to the timing of medical claims submissions and the payment of claims. In turn, Act 142-2020 prohibits providers' medical criteria regarding patients' treatments from being altered by insurers or health management organizations; while also requiring insurers or health management organizations to provide coverage of prescription drugs during the medical exception request process and sets the standard for payments to pharmacies for the initial drugs dispensed during this process. See Comp., at ¶ 3. Act 138 went into effect on November 30, 2020, and Act 142 went into effect on December 8, 2020. Id.

Plaintiffs claim that "[e]ach of these federal programs contains an express preemption clause like the one considered in *[Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Emanuelli-Hernández*, No. CV 19-1940 (SCC), 2021 WL 792742 at *10 (D.P.R. Mar. 1, 2021)], prohibiting the Commonwealth from dictating the rules under which these plans operate." Docket No. 47 at p. 7. Accordingly, Plaintiffs seek declaratory and injunctive relief against the enforcement of both Acts. Id.

Defendants in *Opposition* argue that "[t]he federal legislation cited by plaintiffs in their Motion for Judgment on the Pleadings does not preempt Act-138-2020 and Act-142-2020" as "the Government is exercising its historic and traditional police power to ensure the health and safety of the citizens and residents of Puerto Rico." Docket No. 53 at p. 31. Hence, according to Defendants, "the presumption against preemption to these laws apply to all healthcare payers and are not related to FEHB or ERISA plans." Id.

The Court is once again called to determine whether federal programs under Medicare Advantage, Medicare Part D, ERISA and FEHB are protected by an express preemption clause against the Commonwealth's attempts to regulate how these plans operate.

I. FACTUAL AND PROCEDURAL BACKGROUND

The Commonwealth of Puerto Rico approved Act 138-2020 and Act 142-2020. Particularly, Act 138-2020 amended Sections 30.020, 30.030, 30.040 and 30.050 of Act No. 77 of the Puerto Rico Insurance Code and Section 6 of Act-5 2014. Comp. at ¶ 29.

Act 138 dictates numerous aspects of claims payment between plans and providers. For instance, it incorporates into Act No. 77 a requirement that insurance companies pay healthcare providers within thirty (30) days of receiving a claim for services rendered, so long as the claim constitutes a clean claim (i.e., clean invoice). Id. at ¶ 30; see 2020 P.R. Law 138, ¶ 2. Act 138 specifically defines a clean claim as one that "has no defect, impropriety or special circumstance, such as the lack of necessary documentation that delays timely payment" while imposing new obligations related to the timing of claims submissions and payments of claims by insurers. Comp. at ¶¶ 31-32; see 2020 P.R. Law 138, § 1(i). In furtherance thereof, the Office of the Insurance Commissioner is directed "to prescribe, by regulations, the minimum content criteria for each type of claim, in order to properly establish the minimum content criteria for each type of clean claim,

according to the service rendered." Id. If a claim satisfies the minimum criteria, the health insurer is required to treat the claim as clean while prohibiting insurers from requiring additional documentation from providers unless the insurer has already specified such a requirement by contract. Id.

The Act further specifies the timeframe for the submission and payment of clean claims, by requiring providers to submit their claims for payment of services rendered within ninety (90) days of service, and that insurers and health service organizations pay clean claims within 30 days of receipt. Id. at § 2; see Comp. at ¶ 33. New requirements on the communications between insurers and providers regarding non-claim claims are also imposed by the Act. For instance, within 15 days of receiving a claim, insurers must notify providers if they determine that the claim cannot be processed. 2020 P.R. Law 138, § 4. The notification must include the outstanding information or documentation needed to process the claim. Id. Should a provider fail to notify within the applicable timeframe, the claim will be considered clean. Id. Once a provider receives notification of a claim's deficiency, they have ten (10) days to respond. Id. Upon receiving the provider's response, insurers have five (5) days to either object to or pay the claim. Id. An insurer's failure to object within the applicable five (5) days, shall result in the claim being considered actionable for payment. Id.; see Comp. at ¶ 34.

Finally, Act 138 orders the Puerto Rico Health Insurance Administration to regulate utilization review processes according to new principles, such as, mandating the utilization review be completed within 48 hours of service; prohibiting the use of retrospective review remedies; and providing that the clinical review criteria established in the Insurance Code shall be used as a reference only, with providers' professional judgments ultimately determining the medical necessity of a service. 2020 P.R. Law 138, § 5; see Comp. at ¶ 35.

In turn, Act 142-2020 amended Sections 2.030, 2.040 and 30.050 of Chapter 2 and Section 4.070 of Chapter 4 of Act 194-2011 of the Puerto Rico Insurance Code. Comp. at ¶ 29. Act 142 essentially regulates the handling of prescription drugs while setting standards for coverage of prescription drugs, as well as standards that health insurers must follow when a patient's claim for drug prescription coverage is denied. Comp. at ¶ 38. Namely, it incorporates a revision of the term "Clinical Review Criteria" for stating that physicians are not obligated to use these guidelines when deciding a patient's treatment plan and, as long as providers conform with generally accepted standards of medical practice, their professional judgment remains the exclusive criteria for determining necessary treatment. Id. at ¶ 39. Health Insurers, Pharmacy Benefit Managers (hereinafter, "PBMs") and other entities that administer pharmacy services are required to provide temporary coverage of prescription drugs during the medical exception process. 2020 P.R. Law 142, § 2(B); Comp. at ¶ 40. The medical exception process is triggered when an enrollee or their prescriber requests coverage of a prescription drug that is not included on the health plan's formulary or seeks access to a non-preferred drug at the same cost sharing level as a preferred drug. Comp. at ¶ 41. While the exception is being considered, the Act mandates coverage of the drug even if the drug is excluded from the plan's formulary. The coverage determination must be made within 48 hours from the date of the receipt of the request, or the date of the receipt of certification, if required by the health insurance organization or insurer, whichever is later. For controlled drugs, the timeframe shall not exceed 24 hours. 2020 P.R. Law 142, § 3(E)(1); see Comp. at ¶ 42. Furthermore, the Act mandates that the insurer, PBM or other applicable entity providing the services pay the pharmacy for the initial dispensed drug while accepting electronic invoicing in lieu of paper. 2020 P.R. Law 142, § 2(B).

Medicare Advantage and Part D plans are highly regulated by the federal government. The Medicare statute and regulations establish a comprehensive and articulated framework governing the benefits that may be covered by Medicare Advantage and Part D plans, how beneficiaries may access such benefits, and other rights and responsibilities related to delivery and payment for healthcare items and services. Comp. at ¶ 45. In the *Complaint*, Plaintiffs claim that federal statutes and regulations directly address the topics covered by Laws 138 and 142. Specifically, Plaintiffs argue that the Medicare laws and regulations directly address the timing and process for payment of claims submitted by providers. For instance, clean claims are defined, prompt payment for non-contracted providers are specified, and provision that provider contracts must include a prompt payment provision that is agreed between the plan and the provider, among others. Comp. at ¶ 47.

The federal statutes and regulations governing Medicare Advantage and Part D also address the medication that may be covered under Medicare Parts B and D and those that cannot be covered, procedures for plans to establish formularies and concurrent drug utilization review systems, and the mandatory processes for plans to process and respond to requests for exceptions to formulary and coverage requirements. Comp. at ¶ 48.

Plaintiffs further allege that 42 C.F.R. Part 422, Subpart M and 42 C.F.R. Part 423, Subpart M and the CMS Parts C & D Grievances, Organization/Coverage Determinations, and Appeals Guidance set forth the standards for Medicare Advantage and Part D plans to follow in making coverage decisions and evaluating beneficiary and provider appeals. Comp. at ¶ 52. Particularly, when Part D sponsors deny coverage of a medication at a point of sale, the Part D plan, "has made a coverage determination that is subject to all applicable coverage determination standards, timelines and requirements . . . and [if] the issue is not resolved at the POS [Point of Sale], the network pharmacy must deliver written notice to the enrollee explaining their right to request a

coverage determination, including an exception, from the plan." Prescription Drug Benefit Manual, Ch. 6, Section 30.2.2; 42 C.F.R. 423.566; see Comp. at ¶ 53.

ERISA-covered health plans are sponsored by employers and employee organizations and provide health benefits to employees. Comp. at ¶ 54. Plaintiffs allege that ERISA "seeks to make the benefits promised by an employer more secure by mandating certain oversight systems and other standard procedures. Those systems and procedures are intended to be uniform" consistent with "Congress's intent to establish the regulation of employee welfare benefit plans as exclusively a federal concern." Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943-44 (2016) (citations and internal quotation marks omitted). Comp. at ¶ 55. As part of its provisions, each ERISA plan sponsor is free to structure its own plan and choose the benefits that will be provided to its employees subject to the minimum requirements set forth by law. Id. at ¶ 56. For instance, the ERISA statutes and regulations address the timing and process for payment of claims and for resolving dispute regarding claims. ERISA regulations also include provisions related to how the plan must decide medical necessity. Id. at ¶ 61. It is also required by the federal ERISA statute that every plan provides summary plan descriptions that advise beneficiaries exactly what processes and benefits apply to the plan. Id. at ¶ 63. Therefore, although every plan is responsible for setting the procedures of coverages that apply to its plan, such plan must satisfy the minimum requirements mandated by federal law. Id. at ¶ 66. According to Plaintiffs, ERISA dictates choices about submission and timing of claims and the drugs that are covered, on what terms are to be made by the ERISA plan sponsors in accord with the minimum standards set forth by law. Comp. at 71.

Likewise, the FEHB Program was established and regulated by the federal government and provides employer-sponsored group health insurance to federal employees, retirees, former

employees as well as their family members. Comp. at ¶ 72. The FEHB creates a framework for the administration of health benefits by establishing the member eligibility requirements, the health services to be covered, and establishing standards that insurance plans must comply with in order to offer policies under the Program. Id. The applicable statute authorizes the Office of Personnel Management (hereinafter, "OPM") to enter into contracts with carriers to provide the federal government's chosen benefits to federal employees on the federal government's terms. Section § 8902(d) requires that a contract between OPM and a carrier "shall contain a detailed statement of benefits offered and shall include such maximums, limitations, exclusions, and other definitions of benefits as [OPM] considers necessary or desirable." 5 U.S.C. § 8902(d); see Comp. at ¶ 74. By statute, OPM is also entitled to "prescribe reasonable minimum standards for health benefits plans described by section 8903 or 8903a of this title and for carriers offering the plans." 5 U.S.C. § 8902(e).

Additionally, the FEHB disposes the timing and process for payment of claims and for resolving disputes regarding claims. See 8 C.F.R. 890.105; Comp. at ¶ 77. According to Plaintiffs, OPM imposes additional requirements on insurers for the processing, payment, and timing of claims during the contracting process. Comp. at ¶ 78. The FEHB Program further imposes standards as to which drugs are covered. Id. at ¶ 79. As to utilization management, Plaintiffs argue that the statute requires that contracts with plans include a requirement to implement hospitalization cost-containment measures, such as measures to verify medical necessity, determine the appropriateness of providing services on an outpatient basis, and case management, among others. Id. at ¶ 80; see 5 U.S.C. § 8902(n). As to prescription-drug benefits, the FEHB program specifies utilization management standards. Comp. at ¶ 81. Therefore, choices about

submission and timing of claims and the drugs that are covered and on what terms are to be made by OPM through contract in accord with the minimum standards set by federal law. Id. at ¶ 82.

Plaintiffs are seeking the following remedies: (1) declare that Act 138-2020 is expressly preempted by Medicare Part C; (2) declare that Act 142-2020 is expressly preempted by Medicare Part C; (3) declare that Act 138-2020 is expressly preempted by Medicare Part D; (4) declare that Act 142-2020 is expressly preempted by Medicare Part D; (5) declare that Act 138-2020 is expressly preempted by ERISA; (6) declare that Act 142-2020 is expressly preempted by ERISA; (7) declare that Act 138-2020 is expressly preempted by FEHB; (8) declare that Act 142-2020 is expressly preempted by FEHB; (9) permanently enjoin Defendants and their agents, servants, employees, and all persons in active concert or participation with them from taking any action under or to enforce Act 138-2020 or Act 142-2020, and; (10) grant Plaintiffs such additional or different relief as it deems just and proper. Comp. at pp. 21-22.

Meanwhile, the Defendants argue that the legal controversies before the Court are clearly distinguishable from those that were before Hon. Silvia Carreño-Coll. In said case, "the court had to determine whether Act 90-2019, which amended section 19.150 of the Insurance Code of Puerto Rico, was preempted by Medicare Part C Act 90-2019 [] approved specifically for MAOs [Medicare Advantage Organizations] as an effort of benefiting providers and stopping the mass exodus of medical professionals leaving Puerto Rico in search of better economic opportunities." Docket No. 53 at p. 11. Likewise, "[t]he language used in Act 138-2020 and Act 140-2020 can in no way be compared with the language contained in Act 90-2019 since the latter laws are of general applicability. Act 138-2020 and Act 142-2020 are directed to commercial insurance plans, and not expressly directed to MAOs." Id. As such, said statutes are not preempted by Medicare Part C, 42 U.S.C. § 1395w-21 *et seq.*, nor Medicare Part D, 42 U.S.C. § 1395w-101 *et seq.* See id. Defendants

also argue that MMAPA et als v. Emmanuelli-Hernández, No. CV 19-1940 (SCC), 2021 WL 792742 (D.P.R. March 1, 2021) *aff'd*, 58 F.4th 5 (1st Cir. 2023) is not a binding precedent as it has not become a final ruling from the First Circuit. See id. However, the Court takes judicial notice that on January 18, 2023, the First Circuit affirmed the District Court's determination that Act 90-2019 is preempted by federal law. See Medicaid and Medicare Advantage Products Ass'n of P.R. v. Emmanuelli-Hernández, 58 F.4th 5 (1st Cir. 2023). Essentially, the First Circuit found that "the Mandated Price Provision is preempted by the plain language of the Medicare Advantage Act's express preemption clause and the Congressional intent it evinces." Id. at 14.

II. LEGAL STANDARD

A. Motion for Judgment on the Pleadings

Federal Rule of Civil Procedure 12(c) provides that a party may move for judgment on the pleadings after the pleadings are closed, but early enough not to delay trial. A motion under Rule 12(c) is treated much the same as a motion under Rule 12(b)(6). Aponte–Torres v. University of Puerto Rico, 445 F.3d 50, 54 (1st Cir.2006). The court must review the facts contained in the pleadings in the light most favorable to the non-movant and draw all reasonable inferences in their favor. Id. "A court may not grant a defendant's Rule 12(c) motion 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" Rivera–Gomez v. de Castro, 843 F.2d 631, 635 (1st Cir.1988) (quoting George C. Frey Ready–Mixed Concrete, Inc. v. Pine Hill Concrete Mix Corp., 554 F.2d 551, 553 (2nd Cir.1977)). To survive a Rule 12(c) motion, a complaint must contain factual allegations that raise a right to relief above the speculative level. Perez–Acevedo v. Rivero–Cubano, 520 F.3d 26, 29 (1st Cir.2008). Under Rule 12(c) there is no resolution of contested facts meaning that the court may enter judgment on the pleadings only if the properly considered facts conclusively establish the movant's

point. R.G. Financial Corp. v. Vergara–Nunez, 446 F.3d 178, 182 (1st Cir.2006) (citing Rivera–Gomez, 843 F.2d at 635).

"Where a motion for judgment on the pleadings introduces materials dehors the records for the court's consideration, the ground rules change." Gulf Coast Bank & Trust Co. v. Reder, 355 F.3d 35, 38 (1st Cir.2004). If the court does not exclude the outside materials, the summary judgment standard governs the disposition of the motion. Id. A court may convert a motion for judgment on the pleadings to a motion for summary judgment when: (1) the party opposing the motion is given adequate notice of the conversion, and (2) is given a reasonable opportunity to present material made pertinent to the motion for summary judgment. Id. (citing Collier v. City of Chicopee, 158 F.3d 601, 603 (1st Cir.1998)). "Express notice is not required." Id.

Inasmuch as the Court is only considering the pleadings submitted by the parties, the Court must decide the instant case pursuant to Fed. R. Civ. P. 12(c) and not under motion for summary judgment standard.

B. Federal Rule of Civil Procedure 12(b)(6)

Federal Rule of Civil Procedure 8(a) requires plaintiffs to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under Bell Atlantic v. Twombly, 550 U.S. 544, 555 (2007), a plaintiff must "provide the grounds of his entitlement [with] more than labels and conclusions." See Ocasio–Hernandez v. Fortuño–Burset, 640 F.3d 1, 12 (1st Cir.2011) ("in order to 'show' an entitlement to relief a complaint must contain enough factual material 'to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).' ") (*quoting* Twombly, 550 U.S. at 555) (citation omitted). Thus, a plaintiff must, and is now required to, present allegations

that "nudge [his] claims across the line from conceivable to plausible" in order to comply with the requirements of Rule 8(a). Id. at 570; See e.g. Ashcroft v. Iqbal, 556 U.S. 662 (2009).

When considering a motion to dismiss, the Court's inquiry occurs in a two-step process under the current context-based "plausibility" standard established by Twombly, 550 U.S. 544, and Iqbal, 556 U.S. 662. "Context based" means that a Plaintiff must allege sufficient facts that comply with the basic elements of the cause of action. See Iqbal, 556 U.S. at 677–679 (concluding that plaintiff's complaint was factually insufficient to substantiate the required elements of a Bivens claim, leaving the complaint with only conclusory statements). First, the Court must "accept as true all of the allegations contained in a complaint [,]" discarding legal conclusions, conclusory statements and factually threadbare recitals of the elements of a cause of action. Iqbal, 556 U.S. at 678. "Yet we need not accept as true legal conclusions from the complaint or 'naked assertion[s]' devoid of 'further factual enhancement.'" Maldonado v. Fontanes, 568 F.3d 263, 268 (1st Cir.2009) (quoting Iqbal, 556 U.S. at 678) (quoting Twombly, 550 U.S. at 557).

Under the second step of the inquiry, the Court must determine whether, based upon all assertions that were not discarded under the first step of the inquiry, the complaint "states a plausible claim for relief." Iqbal, 556 U.S. at 679. This second step is "context-specific" and requires that the Court draw from its own "judicial experience and common sense" to decide whether a plaintiff has stated a claim upon which relief may be granted, or, conversely, whether dismissal under Rule 12(b)(6) is appropriate. Id.

Thus, "[i]n order to survive a motion to dismiss, [a] plaintiff must allege sufficient facts to show that he has a plausible entitlement to relief." Sánchez v. Pereira–Castillo, 590 F.3d 31, 41 (1st Cir.2009). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show [n]' 'that the pleader is

entitled to relief.'" Iqbal, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)). Furthermore, such inferences must be at least as plausible as any "obvious alternative explanation." Id. at 682 (*citing* Twombly, 550 U.S. at 567).

The First Circuit has cautioned against equating plausibility with an analysis of the likely success on the merits, affirming that the plausibility standard assumes "pleaded facts to be true and read in a plaintiff's favor" "even if seemingly incredible." Sepúlveda–Villarini v. Dep't of Educ. of P.R., 628 F.3d 25, 30 (1st Cir.2010) (*citing* Twombly, 550 U.S. at 556); Ocasio–Hernández, 640 F.3d at 12 (citing *Iqbal*, 556 U.S. at 679); See Twombly, 550 U.S. at 556 ("[A] well-pleaded complaint may proceed even if it appears that a recovery is very remote and unlikely.") (internal quotation marks omitted); See Ocasio–Hernández, 640 F.3d at 12 (*citing* Twombly, 550 U.S. at 556, 127 S.Ct. 1955) ("[T]he court may not disregard properly pled factual allegations, 'even if it strikes a savvy judge that actual proof of those facts is improbable.'"). Instead, the First Circuit has emphasized that "[t]he make-or-break standard ... is that the combined allegations, taken as true, must state a plausible, [but] not a merely conceivable, case for relief." Sepúlveda–Villarini, 628 F.3d at 29.

However, a complaint that rests on "bald assertions, unsupportable conclusions, periphrastic circumlocutions, and the like" will likely not survive a motion to dismiss. Aulson v. Blanchard, 83 F.3d 1, 3 (1st Cir.1996). Similarly, unadorned factual assertions as to the elements of the cause of action are inadequate as well. Penalbert–Rosa v. Fortuño–Burset, 631 F.3d 592 (1st Cir.2011). "Specific information, even if not in the form of admissible evidence, would likely be enough at [the motion to dismiss] stage; pure speculation is not." Id. at 596; See Iqbal, 556 U.S. at 681 ("To be clear, we do not reject [ ] bald allegations on the ground that they are unrealistic or nonsensical.... It is the conclusory nature of [the] allegations, rather than their extravagantly

fanciful nature, that disentitles them to the presumption of truth."); See Mendez Internet Mgmt. Servs. v. Banco Santander de P.R., 621 F.3d 10, 14 (1st Cir.2010) (the Twombly and Iqbal standards require District Courts to "screen[ ] out rhetoric masquerading as litigation."). However, merely parroting the elements of a cause of action is insufficient. Ocasio–Hernández, 640 F.3d at 12 (citing Sánchez v. Pereira–Castillo, 590 F.3d 31, 49 (1st Cir.2009)).

III. LEGAL ANALYSIS

A. Express Preemption

Under the Supremacy Clause of Article VI of the Constitution, "[w]hen Congress has expressly so provided, federal preemption of state law is mandated." Rosario–Cordero v. Crowley Towing & Transp. Co., 46 F.3d 120, 122 (1st Cir.1995). As such, "[a]ny state law that contravenes a federal law is null and void." Tobin v. Fed. Exp. Corp., 775 F.3d 448, 452 (1st Cir. 2014). "Federal preemption of state law may occur either expressly or by implication." Brown v. United Airlines, Inc., 720 F.3d 60, 63 (1st Cir. 2013).

Therefore, "[t]he issue of preemption "requires an examination of congressional intent." Schneidewind v. ANR Pipeline Co., 485 U.S.293, 299, 108 S.Ct. 1145, 99 L.Ed.2d 316 (1988). "Congress explicitly may define the extent to which its enactments pre-empt state law." Id. (*citing* Shaw, 463 U.S. at 95–96, 103 S.Ct. 2890). Express preemption exists "when a federal statute explicitly confirms Congress's intention to preempt state law and defines the extent of that preclusion." Grant's Dairy–Maine v. Commissioner of Maine, 232 F.3d 8, 15 (1st Cir.2000). "Congressional intent is the touchstone of any effort to map the boundaries of an express preemption provision." Tobin, 775 F.3d at 452. Accordingly, "when Congress has made its intent known through explicit statutory language, the courts' task is an easy one." English v. General Electric Co., 496 U.S. 72, 79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990).

Notably, when the statute "'contains an express pre-emption clause,' [the Court does] not invoke any presumption against pre-emption but instead 'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" Puerto Rico v. Franklin California Tax-Free Tr., 579 U.S. 115, 125, 136 S. Ct. 1938, 1946, 195 L. Ed. 2d 298 (2016) (*quoting* Chamber of Commerce of United States of America v. Whiting, 563 U.S. 582, 594, 131 S.Ct. 1968, 179 L.Ed.2d 1031 (2011)). Therefore, if a statute contains a specific preemption clause, the Court's inquiry is simplified.

However, when express preemption is absent, implied preemption may arise. Namely, "[a]bsent explicit pre-emptive language, [the Supreme Court has recognized] at least two types of implied pre-emption: field pre-emption, where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, and conflict pre-emption, where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress . . ." Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98, 112 S. Ct. 2374, 2383, 120 L. Ed. 2d 73 (1992)(internal citations omitted).

The Court previously determined that Plaintiffs complied with raising plausible claims for relief as to whether Act 138-2020 and Act 142-2020 are preempted by Medicare, ERISA and/or FEHB. See Docket No. 43. However, as seeking summary judgment was not the proper mechanism to seek a remedy at such an early stage of the proceedings, the Court denied the summary judgment request and instead found that "Plaintiffs may move for dismissal once the pleadings stage concludes." Id. at p. 26. Plaintiffs have now moved for judgment on the pleadings, essentially arguing that,

> [a]t every turn, Act 138 and Act 142 inject supplemental requirements onto Medicare, ERISA, and FEHB plans that are straightforwardly preempted. Through

> each express preemption provision, Congress expressly provided that the operation of these plans under federal programs is governed by federal law, and Puerto Rico cannot set its own standards. There are no issues of fact, and plaintiffs are entitled to judgment as a matter of law.

Docket No. 47-1 at p. 13. "The bottom line for each preemption provision is that state laws cannot regulate the operation of plans governed by each of these federal programs." Id.

In turn, the Defendants claim that "the Preemption Clause in Medicare Part C and Part D clearly preempts state regulation only if a Medicare 'standard' particularly addresses the subject of state regulation. And because the challenged provisions of Act 138-2020 and Act 142-2020 does not dictate standards with respect to Medicare Advantage Plans or overlap with existing federal standards under Medicare Part C, they fall outside of the Medicare preemption scope." Docket No. 53 at p. 3. It is further argued that "the [Government of Puerto Rico and the Office of the Insurance Commissioner] OIC has jurisdiction over MAO's prompt payment obligations only when they have failed to include a prompt payment clause in their contract." Lastly, as to plaintiffs who provide ERISA and FEHB plan administration, Defendants claim that "Act 138-2020 and Act 142-2020 (which are laws of general applicability) have only a 'tenuous, remote or peripheral connection with covered plans' and therefore, cannot be found to be preempted." Id.; see New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995).

In order to illuminate this intent, the Court begins with the text and context of each federal provision individually.

1) Medicare

Medicare is a federal health insurance program established under Title XVIII of the Social Security Act for people who are 65 years and older and some younger people with certain disabilities or end-stage renal disease. It is administered by the Secretary of Health and Human

Services through the Centers for Medicare and Medicaid Service (hereinafter, "CMS"), and consists of four (4) parts. See Medicare Program; Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588 (Jan. 28, 2005).

"A Medicare Administrative Contractor (MAC) is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B medical claims or Durable Medical Equipment (DME) claims for Medicare Fee-For Service (FFS) beneficiaries." CMS. *What is a MAC*, https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC#WhatIsAMac (visited March 14, 2022). "Under the traditional Medicare program, the government pays healthcare providers directly based on a fee-for-services schedule devised by CMS." Medicaid & Medicare Advantage Prod. Ass'n of Puerto Rico, Inc. v. Emanuelli-Hernandez, 2021 WL 792742 at *2 (D.P.R. Mar. 1, 2021).

However, under Medicare Part C (also known as "Medicare Advantage"), CMS contracts with the private Medicare Advantage organizations, who in turn contract with healthcare providers, to provide bundled Medicare plans to MA beneficiaries." Id. (internal quotations omitted). Therefore, Medicare Advantage ("hereinafter, "MA") expanded Medicare's beneficiaries' insurance choices to private plans "with coordinated care and more comprehensive benefits" than those traditionally provided under Medicare. See id. Likewise, private companies offer Medicare Part D, which provides an optional prescription drug coverage for beneficiaries who select it, under contract with CMS. See Docket No. 47-1 at p. 8. Medicare Advantage organizations receive a per-person monthly payment to provide coverage under Part C and Part D plans. See Medicaid & Medicare Advantage Prod. Ass'n of Puerto Rico, Inc., 2021 WL 792742 at *2. But "[t]he federal government also contributes toward some individual Part D claims through

a low-income cost-sharing subsidy, catastrophic reinsurance, and risk corridors." Docket No. 47-1 at p. 8.

As previously explained, "[c]ongressional intent is the touchstone of any effort to map the boundaries of an express preemption provision." Tobin, 775 F.3d at 452. Therefore, we turn to the state and federal law at issue, starting with the plain language of the Preemption Provision of the Medicare Advantage Act. Firstly, the standards established under Medicare Part C "shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." 42 U.S.C. § 1395w-26(b)(3). This section is equally applicable to Medicare Part D. See 42 U.S.C. § 1395w-112(g). Hence, "[t]he legislative history of this provision clarified that 'the [Medicare Advantage Program] is a federal program operated under Federal rules and that State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency.'" First Med. Health Plan, Inc. v. Vega-Ramos, 479 F.3d 46, 51 (1st Cir. 2007) (*quoting* H. Conf. Rep. 108–391 at 557, *reprinted in* 2003 U.S.C.C.A.N. at 1926).

On a similar basis, on January 18, 2023, the First Circuit found that Act 90-2019, requiring that Medicare Advantage plans compensate healthcare providers in Puerto Rico at the same rate as providers are compensated under traditional Medicare, is preempted by federal law. See Medicaid and Medicare Advantage Products Ass'n of P.R. v. Emmanuelli-Hernández, 58 F.4th 5 (1st Cir. 2023). Essentially, the First Circuit determined that "the Mandated Price Provision is preempted by the plain language of the Medicare Advantage Act's express preemption clause and the Congressional intent it evinces." Id.

2) Employment Retirement Income Security Act of 1974 ("ERISA")

The Employment Retirement Income Security Act of 1974 ("ERISA") is a "federal law that sets minimum standards for most voluntarily established retirement and health plans in private industry to provide protection for individuals in these plans." *Employee Retirement Income Security Act (ERISA)*, U.S. DEP'T OF LAB., https://www.dol.gov/general/topic/health-plans/erisa (last visited March 14, 2021). ERISA "does not go about protecting plan participants and their beneficiaries by requiring employers to provide any given set of minimum benefits, but instead controls the administration of benefit plans … ." New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 651, 115 S. Ct. 1671, 1674, 131 L. Ed. 2d 695 (1995). Accordingly, ERISA's "systems and procedures are intended to be uniform." Gobeille, 577 U.S. at 321, 136 S. Ct. at 944. In fact, "[r]equiring ERISA administrators to master the relevant laws of 50 States and to contend with litigation would undermine the congressional goal of 'minimiz[ing] the administrative and financial burden[s]' on plan administrators—burdens ultimately borne by the beneficiaries." Id.

ERISA also includes an express preemption provision, which provides in its pertinent part that "the provisions of this subchapter … shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a)(emphasis ours). Evidently, "[o]ne of the principal goals of ERISA is to enable employers 'to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits,' Egelhoff v. Egelhoff ex rel. Breiner, 532 U.S. 141, 148, 121 S. Ct. 1322, 1328, 149 L. Ed. 2d 264 (2001) (*quoting* Fort Halifax Packing Co. v. Coyne, 482 U.S. 1, 9, 107 S.Ct. 2211, 96 L.Ed.2d 1 (1987)). Therefore, "[u]niformity is impossible ... if plans are subject to different legal obligations in different States." Id. Lastly, pursuant to Supreme Court precedent,

ERISA's express preemption provision demonstrates "Congress's intent to establish the regulation of employee welfare benefit plans 'as exclusively a federal concern.'" Travelers, 514 U.S. at 656, 115 S. Ct. at 1671 (*quoting* Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504, 505, 101 S. Ct. 1895, 1897, 68 L. Ed. 2d 402 (1981))(emphasis ours).

Implementing these provisions there are two categories of state laws preempted by ERISA. Firstly, "ERISA pre-empts a state law if it has 'reference to' ERISA plans." Gobeille, 577 U.S. at 320, 136 S. Ct. at 944. Specifically, "[w]here a State's law acts immediately and exclusively upon ERISA plans, … or where the existence of ERISA plans is essential to the law's operation, … that 'reference' will result in pre-emption." California Div. of Lab. Standards Enf't v. Dillingham Const., N.A., Inc., 519 U.S. 316, 325, 117 S. Ct. 832, 838, 136 L. Ed. 2d 791 (1997). Secondly, "[a] state law also might have an impermissible connection with ERISA plans if 'acute, albeit indirect, economic effects' of the state law 'force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.'" Gobeille, 577 U.S. at 320, 136 S. Ct. at 943. Ultimately, preemption of "[d]iffering, or even parallel regulations from multiple jurisdictions," are necessary in order to "prevent the States from imposing novel, inconsistent, and burdensome" legislation. Id. at 323, 136 S. Ct. at 945.

3) Federal Employees Health Benefits ("FEHB")

The Federal Employees Health Benefits Program ("FEHB") was established and regulated by the federal government and provides employer-sponsored group health insurance to federal employees, retirees, former employees as well as their family members. Comp. at ¶ 72. The FEHB provides the legal framework for the administration of health benefits by establishing the member eligibility requirements, the health services to be covered, and establishing standards that insurance plans must comply with in order to offer policies under the Program. Id. The applicable statute

authorizes the OPM to enter into contracts with carriers to provide the federal government's chosen benefits to federal employees on the federal government's terms. See 5 U.S.C. § 8902(d), (e). The federal government contributes a portion of the premium necessary to provide coverage to its employees. Id. at § 8906.

The FEHB program also includes an express preemption provision, which reads as follows:

> The terms of any contract under this chapter which relate to the nature, provision, or extent of coverage or benefits (including payments with respect to benefits) shall supersede and preempt any State or local law, or any regulation issued thereunder, which relates to health insurance or plans.

5 U.S.C. § 8902(m)(1). The Supreme Court has "'repeatedly recognized'" that the phrase 'relate to' in a preemption clause 'express[es] a broad pre-emptive purpose.' Congress characteristically employs the phrase to reach any subject that has 'a connection with, or reference to,' the topics the statute enumerates." Coventry Health Care of Missouri, Inc. v. Nevils, 137 S. Ct. 1190, 1197, 197 L. Ed. 2d 572 (2017) (internal quotations omitted).

Notably, the "FEHBA concerns 'benefits from a federal health insurance plan for federal employees that arise from a federal law." Coventry, 137 S. Ct. at 1193, 197 (*quoting* Bell v. Blue Cross & Blue Shield of Oklahoma, 823 F.3d 1198, 1201–02 (8th Cir. 2016)) (internal quotations omitted). Therefore, "strong and 'distinctly federal interests are involved.'" Coventry, 137 S. Ct. at 1193 (*quoting* Bell, 823 F.3d at 1202). The Eight Circuit has emphasized that, "[a]lthough health care in general is an area of traditional state regulation, this dispute concerns benefits from a federal health insurance plan for federal employees that arise from a federal law. There is obviously a long history of federal involvement in federal employment and benefits." Bell, 823 F.3d at 1202 (internal citations omitted).

B. Dismissal under 12(c)

In this case, Plaintiffs claim that "Act 138 and Act 142 inject supplemental requirements onto Medicare, ERISA, and FEHB plans that are straightforwardly preempted. Through each express preemption provision, Congress expressly provided that the operation of these plans under federal programs is governed by federal law, and Puerto Rico cannot set its own standards." Docket No. 41-1 at p. 13. As such, there are no issues of fact which impede judgment in favor of Plaintiffs as a matter of law. See id.

In *Opposition*, Defendants argue that Act 138-2020 "does not specifically mention or is specifically directed to Medicare Part C or D, ERISA or FEHB plans." Docket No. 53 at p. 7. In fact,

> "[n]othing in the Act contravenes or overrides the claims payments process as established in federal law. Clarification and scope of what a clean claim is, as delineated in federal law, and the payment process to be followed to receive said payment (clean claim *vis a vis* unprocessable claim), does not clash with the federally dictated standard."

Id.

In turn, as to Act 142-2020, the Defendants claim that the definition of clinical review criteria "is consistent with federal laws and regulations on this topic. Therefore, Act 142-2020 looks to avoid harm to patients for not receiving their prescription medication and treatments due to hurdles in the claim process and to strengthen healthcare professional's income." Id. at p. 8. Lastly, the Defendants argue that Act 142-2020 includes a Severability clause which states as follows:

> If any clause, paragraph, subparagraph, sentence, word, letter, article, provision, section, subsection, title, chapter, subchapter, heading, or part of this Act were to be held to be null or unconstitutional, the ruling, holding, or judgment to such effect shall not affect, impair or invalidate the remainder of this Act.
>
> […]

> It is the express an unequivocal will of this Legislative Assembly that the courts enforce the provisions and application of this Act, even if it renders ineffective, nullifies, invalidates, impairs or holds to be unconstitutional any part thereof, or even if it renders ineffective, invalidates, or holds to be unconstitutional the application thereof to any person or circumstance.

2020 Laws Ann. Tit. 142.

Lastly, the Defendants argue that Act 90-2019[1] is distinguishable from the language used in Act 138-2020 and Act 142-2020 as "the latter laws are of general applicability. Act 138-2020 and Act 142- 2020 are directed to commercial insurance plans, and not expressly directed to MAOs. As a result, they are not preempted by Medicare Part C, 42 U.S.C. § 1395w-21 et seq., nor Medicare Part D, 42 U.S.C. § 1395w-101 et seq." Docket No. 53 at p. 12.

i. Act 138-2020 and Act 142-2020 are preempted by Medicare Part C and Part D

Medicare Parts C and D are protected by the plain language of an express preemption provision which reads as follows: "[t]he standards established under this part shall supersede any State law or regulation . . . with respect to MA [or Part D] plans which are offered by MA organizations [or Part D plan sponsors] under this part." 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g). "The legislative history of this provision clarified that 'the [Medicare Advantage Program] is a federal program operated under Federal rules and that State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency.'" First Med. Health Plan, Inc. v. Vega-Ramos, 479 F.3d 46, 51 (1st Cir. 2007) (quoting H.R. Rep. No. 108-391, at 557). "Prior to its amendment in 2003, the preemption clause read as follows: [t]he standards established under this subsection shall supersede any State law or regulation . . . with respect to

[1] On January 18, 2023, the First Circuit determined that "the Mandated Price Provision [in Act 90-2019] is preempted by the plain language of the Medicare Advantage Act's express preemption clause and the Congressional intent it evinces." Medicaid and Medicare Advantage Products Ass'n of P.R. v. Emmanuelli-Hernández, 58 F.4th 5, 14 (1st Cir. 2023).

[Medicare Part C] plans . . . to the extent or regulation is inconsistent with such standards. ..." Medicaid & Medicare Advantage Prod. Ass'n of Puerto Rico, Inc. v. Emanuelli Hernandez, 58 F.4th at 12; see 42 U.S.C. § 1395w-26(b)(3)(A) (2002). By amending the preemption clause in 2003 Congress the requirement that a state law be "inconsistent with" federal standards to be preempted was removed. See id. By amending the preemption provision to include the broad language that "any state law or regulation" is superseded by federal law, Congress intended to fully preempt State laws while emphasizing that Medicare is "a Federal program and that State laws should not apply." Medicare Program; Establishment of the Medicare Advantage Program, 70 FR 4588-01. Simply expressed, "the effect of the 2003 amendment was to expand the scope of express Medicare preemption from conflict preemption to field preemption." Pharm. Care Mgmt. Ass'n v. Wehbi, 18 F.4th 956, 971 (8th Cir. 2021).

Therefore, as correctly noted by the District Court, "[t]he Preemption Provision clearly states in the broadest of terms that Medicare Part C supersedes all regulation by the States of MA plans offered by MAOs, with only two explicitly delineated exceptions, neither of which are applicable here," namely, state licensing laws or state laws related to plan solvency. Medicaid & Medicare Advantage Prod. Ass'n of Puerto Rico, Inc. v. Emanuelli-Hernandez, 2021 WL 792742 (D.P.R. Mar. 1, 2021), *aff'd*, 58 F.4th 5 (1st Cir. 2023).

While the Defendants argue that "[A]ct 138-2020 and Act 142-2020 do not dictate standards with respect to MA plans or overlap with existing federal standards under Medicare Par C or Part D, [thus] they fall outside the preemption scope of the MAA," it is evident that the preemption clause extends preemption in the broadest of terms to any state law or regulation with respect to Medicare. See Docket No. 53 at 15. The only two limitations provided by statute hold no relation to Act 138-2020 and Act 142-2020. As such, both state laws are preempted by federal

law as to Medicare Part C and D. The supremacy clause is insufficient to cure this deficiency. Therefore, the Court agrees with Plaintiffs inasmuch as "any state law regulating Part C or Part D plans is 'superseded' if it falls within the area of regulation within which Congress determined that CMS alone should set the standards." Docket No. 47-1 at 14. These are federal programs that must be administered and regulated by federal authorities.

ii. ERISA preempts state laws from governing the operation of ERISA plans

Similarly, ERISA includes an express preemption provision, which provides in its pertinent part that "the provisions of this subchapter … shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a) (emphasis ours). Pursuant to Supreme Court precedent, the ERISA "systems and procedures are intended to be uniform." Gobeille, 577 U.S. at 321, 136 S. Ct. at 944. The ERISA provision clearly demonstrates that "that Congress meant to establish pension plan regulation as exclusively a federal concern." Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504, 505, 101 S. Ct. 1895, 1897, 68 L. Ed. 2d 402 (1981). Importantly, "[r]equiring administrators to master the relevant laws of 50 States and to contend with litigation would undermine the congressional goal of minimizing their administrative and financial burdens." Egelhoff v. Egelhoff ex rel. Breiner, 532 U.S. 141, 142, 121 S. Ct. 1322, 1325, 149 L. Ed. 2d 264 (2001). The Supreme Court has been very specific as to the two (2) categories of state laws that ERISA preempts. To wit,

> [f]irst, ERISA pre-empts a state law if it has a reference to ERISA plans. To be more precise, where a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation . . ., that reference will result in preemption. Second, ERISA pre-empts a state law that has an impermissible connection with ERISA plans, meaning a state law that governs ... a central matter of plan administration or interferes with nationally uniform plan administration.

Gobeille, 577 U.S. at 319, 136 S. Ct. at 943 (internal citations omitted). Therefore, "[p]re-emption is necessary in order to prevent multiple jurisdictions from imposing differing, or even parallel, regulations, creating wasteful administrative costs and threatening to subject plans to wide-ranging liability." Id. at 939.

Under this scenario, Defendants claim that "[b]oth Act 138-2020 and Act 142-2020, . . . are laws of general applicability, [which] have only a 'tenuous, remote, or peripheral connection with covered plans' and therefore, cannot be found to be preempted." Docket No. 53 at p. 26. But ultimately, "these provisions are consistent with federal laws and regulations." Id. at p. 8. Notably, in their *Reply*, Plaintiffs argue that the Defendants ignore well-settled ERISA inasmuch as,

> [t]hat assertion cannot be squared with the Supreme Court's ERISA precedents. State laws requiring plans to process claims in certain ways and on certain timetables, and requiring plans to cover drugs in certain ways, strike at the very core of benefit design and administration and thus fall squarely within ERISA's preemption clause. In asserting otherwise, defendants simply ignore decades of Supreme Court precedent.

Docket No. 60 at p. 15. Essentially, "ERISA's provisions and the implementation of those provisions through ERISA plan terms already regulate the claims payment process. Importantly, "[d]iffering state regulations affecting an ERISA plan's system for processing claims and paying benefits impose precisely the burden that ERISA pre-emption was intended to avoid." Egelhoff, 532 U.S. at 142. Thus, federal regulation is intended to prevail over state regulations as to ERISA plans.

The Court notes that ERISA was designed in order to provide "a single uniform national scheme for the administration of ERISA plans without interference from the laws of the several States even when those laws, to a large extent, impose parallel requirements." Gobeille, 577 U.S. at 326-27. That way, administrative and financial burdens that differing state laws would entail would be minimized. See Egelhoff, 532 U.S. at 142. As such, federal law governs ERISA plans,

displacing state laws on regulating on the same topics regardless of whether they are consistent, conflicting, parallel, or perpendicular. And ultimately, state laws or statutes that intrude upon a central matter of plan administration and interfere with ERISA's national uniform plan administration are preempted as to ERISA plans, even if other entities are subject to complying with it. See *e.g.*, Gobeille, 577 U.S. at 321.

As previously explained in detail[2] (see pp. 7-8 of this *Opinion)*, Act 138-2020 regulates several aspects of claims payments between plans and providers. For instance, a "clean claim" is defined as one that "has no defect, impropriety or special circumstance, such as the lack of necessary documentation that delays timely payment." 2020 P.R. Law 138 §§ 2, 1(j). Pursuant to Act 138-2020, insurers are to treat a claim as "clean" so long as it satisfies the minimum criteria set forth by the Office of the Insurance Commissioner. Additionally, Act 138-2020 imposes a particular timing of claim submission and payment. In case of non-clean claims, Act 138-2020 establishes a procedure between insurers and providers in order to expedite the payment. Lastly, the utilization review processes are ordered to be regulated by the Puerto Rico Health Insurance Administration under new principles, providing the clinical review criteria as reference only and amplifying the professional providers' criteria as the exclusive criteria for determining the medical necessity of a service.

Meanwhile, Act 142-2020 redefines clinical review criteria as "the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a health insurance organization or insurer to determine the medical necessity and appropriateness of healthcare." 2020 P.R. Law 142. The guidelines are not mandatory for a health professional so long as the services rendered are recognized as accepted standards for the practice of medicine and

[2] See pp. 7-9 of this *Opinion*.

accepted in the general community. In addition, Section 4.070 provides that the health insurance organization or insurer that provides prescription drug benefits, the PMB or any other entity, shall offer coverage and provide a one-time fill medication while the medical exception request is being evaluated and a final determination given. Id. Followed, a coverage determination shall be made within forty-eight (48) hours.

ERISA already regulates the claims payment process, utilization review, and clinical review criteria applicable to ERISA plans that the Government of Puerto Rico is trying to regulate through Act 138-2020. As to Act 142-2020 a similar situation is encountered. ERISA plans already have structures governing issues as to temporary coverage for prescription drugs during the medical exception request process, plus reasonable notifications and determinations, the ERISA plan's clinical review criteria definition and one-time fill medication dispense of non-covered drugs to pharmacies. This results in state regulations that are impermissibly related to federal plans. Allowing federal and state laws to coexist would result in an impermissible overlapping that the express preemption provision is designed to prevent. Therefore, Act 138-2020 and Act 142-2020 may be applicable to other commercial health insurers but are preempted as to ERISA plans.

iii. FEHB preempts state laws from governing the operation of FEHB plans

Likewise, FEHB also has an express preemption provision which provides that,

> [t]he terms of any contract under this chapter which relate to the nature, provision, or extent of coverage or benefits (including payments with respect to benefits) shall supersede and preempt any State or local law, or any regulation issued thereunder, which relates to health insurance or plans.

5 U.S.C. § 8902(m)(1). As such, "FEHBA concerns 'benefits from a federal health insurance plan for federal employees that arise from a federal law' in an area with a 'long history of federal involvement.' Coventry Health Care of Missouri, Inc. v. Nevils, 581 U.S. 87, 96, 137 S. Ct. 1190, 1197, 197 L. Ed. 2d 572 (2017) (quoting Bell v. Blue Cross and Blue Shield of Oklahoma, 823

F.3d 1198, 1202 (8th Cir. 2016). In sum, "there are strong and distinctly federal interests [] involved, in uniform administration of the program, free from state interference, particularly in regard to coverage, benefits, and payments." Id. Just like in the ERISA plans, Congress' use of the phrase "relate to" in a preemption clause "to reach any subject that has a 'connection with, or reference to,' the topics the statute enumerates." Id. (quoting Morales v. TransWorld Airlines, Inc., 504 U.S. 374, 384, 112 S.Ct. 2031, 119 L.Ed.2d 157 (1992).

Congress' 1998 amendment to FEHB preemption clause is very telling. Before the amendment, the FEHB preemption statute applied only "to the extent that such [state] law or regulation is inconsistent with contractual provisions." 5 U.S.C. § 8902(m)(1) (1997). But by amending the statute, Congress struck the requirement of inconsistency.

Here, the Court encounters a similar scenario as to ERISA plans. As previously explained in detail[3], FEHB plans are governed by the FEHB statute and OPM contracts made pursuant thereto. In fact, FEHB already regulates the claims payment process, utilization review, and clinical review criteria applicable to FEHB plans that the Government of Puerto Rico is trying to regulate through Act 138-2020. With relation to Act 142-2020, FEHB plans already have structures governing issues as to temporary coverage for prescription drugs during the medical exception request process, plus reasonable notifications, and determinations, the FEHB plan's clinical review criteria definition and one-time fill medication dispense of non-covered drugs to pharmacies. This results in state regulations that are impermissibly related to federal plans. Allowing federal and state laws to coexist would result in an impermissible overlapping that the express preemption provision is designed to prevent.

[3] See pp. 8-9 of this *Opinion*.

In any event, Defendants argument that "Act 138-2020 nor Act 142-2020 create a scheme that changes the administrative proceedings established by OPM" constitutes an admission that these laws do regulate FEHB plans. Thus, they are preempted as FEHB provisions "shall supersede and preempt any State or local law, or any regulation issued thereunder, which relates to health insurance or plans." 5 U.S.C. § 8902(m)(1).

C. McCarran-Ferguson Act

Upon the enactment of the McCarran-Ferguson Act, Congress effectively acknowledged the regulation by the states of the insurance of business. *See* 15 U.S.C. §§ 101, *et seq.* Specifically, Section 2(a) of the provides in its pertinent part that "[t]he business of insurance, and every person engaged therein, shall be subject to the laws of the several States which relate to the regulation or taxation of such business." 15 U.S.C. § 1012. Accordingly, "[t]hose two provisions reverse the ordinary rules of preemption which holds that federal law preempts state law by virtue of the Supremacy Clause." *Advance Cellular Sys. v. Mayol (In re: Advance Cellular Sys.)*, 235 B.R. 713, 718 (U.S.B.C. PR, 1999).

Here, the Defendants claim that if a state law regulates insurance, it is not preempted. *See* Docket No. 53 at p. 30. In fact, "[r]everse preemption, as recognized by Congress in the McCarran-Ferguson Act, does not recognize an either-or choice between healthcare and insurance, when deciding a preemption case." Id. As such, the areas that are covered by Act 138-2020 and Act 142-2020 "historically have been of local concern, and therefore, cannot be preempted." Id. at p. 31.

But as Plaintiffs correctly point out, reverse-preemption is expressly inapplicable to ERISA, as it "obviously and specifically relates to the business of insurance," and accordingly, "the McCarran–Ferguson Act does not surrender regulation exclusively to the States so as to preclude the application of ERISA to an insurer's actions under a general account contract." John

Hancock Mut. Life Ins. Co. v. Harris Tr. & Sav. Bank, 510 U.S. 86, 98, 114 S. Ct. 517, 525, 126 L. Ed. 2d 524 (1993). And ultimately, "ERISA is materially indistinguishable from Medicare and FEHB under the [McCarran-Ferguson Act]." Docket No. 60 at p. 14. In any event, Medicare and FEHB are not considered to be in the business of insurance. *See* United States v. Rhode Island Insurers' Insolvency Fund, 80 F.3d 616, 620 (1st Cir. 1996). Therefore, the Defendants' argument pursuant to the McCarran-Ferguson Act is unfounded.

IV. CONCLUSION

Upon a careful review of the parties' arguments, the Court hereby **GRANTS** Plaintiffs' *Motion for Judgment on the Pleadings* (Docket No. 47). Accordingly, the Court hereby enters declaratory judgment that Act 138-2020 (2020 P.R. Law 138) amending Sections 30.020, 30.030, 30.040 and 30.050 of Act No. 77 of the Puerto Rico Insurance Code and Section 6 of Act-5 2014; and Act 142-2020 (2020 P.R. Law 142) amending Sections 2.030, 2.040 and 30.050 of Chapter 2 and Section 4.070 of Chapter 4 of Act 194-2011 of the Puerto Rico Insurance Code are expressly preempted by the Medicare Advantage program, Medicare Part D, the Federal Employee Retirement Income Security Act of 1974, and the Federal Employees Health Benefits program[4].

IT IS SO ORDERED.

In San Juan, Puerto Rico, this 8th day of March, 2023.

S/Daniel R. Domínguez
Daniel R. Domínguez
United States District Judge

[4] As the Court found that Act 138-2020 and Act 142-2020 are preempted by federal health programs, the Court needs not delve into Defendants' ripeness arguments as they are inapplicable, and in any event, MOOT.